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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,579	11/02/2000	Brian M. Fendly	P1053R1D1	5667

7590 07/12/2006
Genentech Inc
Wendy M Lee
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/705,579		FENDLY, BRIAN M.	
	Examiner		Art Unit	
	Christopher H. Yaen		1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 71 is/are allowed.
- 6) ☒ Claim(s) 69 is/are rejected.
- 7) ☒ Claim(s) 70 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 November 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: FENDLY, BRIAN M

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/19/2006 has been entered.
2. The amendment filed 4/19/2006 is acknowledged and entered into the record. Accordingly, claims 1-68 are canceled without prejudice or disclaimer, and claims 70-71 are newly added.
3. Claims 69-71 are pending and examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claim 69 under 35 USC § 103(a) as being obvious over Hudziak *et al* (US Patent 5,720,954) in view of Pauwels *et al* (J. Pharmacol. Oct. 1995; 47(10):870-875) is maintained for the reasons of record. Applicant argues that the combination of the anti-Her2 antibody which binds to an ErbB2 epitope bound by deposited antibody 4D5 in combination with Vinorelbine for the treatment of breast

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cancer is deemed an unexpected result. Applicant supports this assertion via the submission of several pieces of data including clinical data from a phase III clinical trial (see papers filed 3/21/2005) as well as a paper published in 1999 showing the current state of the art with regard to the combination of humanized 4D5 (i.e. rhuMAb HER2) and Vinorelbine (see Pegram *et al*/ Oncogene 1999; 182241-2251). Applicant also argues that the exhibits filed to support the unexpected results of humanized 4D5 in combination with vinorelbine is commensurate in scope to the instant claims and is indicative of the broad genus of "antibodies which bind to an ErbB2 epitope bound by antibody 4D5" because those of skill in that art would be capable of making antibodies which bind to the same epitope bound by 4D5. Applicant asserts that those of skill in the art have made other antibodies that bind to the same epitope as 4D5 (e.g. 3H4) and indicate that through epitope mapping studies that this antibody was capable of blocking the binding of the 4d5 antibody. Applicant concludes that those of skill in the art would be capable of making such antibodies and such antibodies would be effective for treating breast cancer. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. Moreover, the burden falls on the applicant to establish that the evidence relied upon should establish

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“that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance.” Ex parte Gelles, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). In the instant case, although the unexpected results pertaining to the use of humanized 4D5 (i.e. rhuMAB HER-2) as disclosed by Pegram *et al* (cited above) is deemed commensurate in scope and persuasive to overcome the 103(a) rejection for claims 70 and 71, the exhibits provided to show unexpected results for “anti-ErbB2 antibodies which binds to an ErbB2 epitope bound by 4D5” in combination with Vinorelbine is not commensurate in scope. The synergistic effect associated with the use of humanized 4D5 and Vinorelbine may not be epitope specific, but rather antibody specific. The data proffered does not indicate that other anti-ErbB2 antibodies can be substituted for the humanized 4D5. The assertions made by applicant regarding the use of other antibodies such as 3H4 (an antibody capable of blocking the binding of 4D5 to its epitope) are unsubstantiated and are merely opinions offered by counsel. The prior art teaches that there are in fact differences in between the 4D5 antibody and its humanized counter part, rhuMAB-HER2. For example, Lewis *et al* (Cancer Immunol. Immunother. 1993;37:255-263, see page 261 for example) teaches that 4D5 lacks effector functions, while the humanized counter part, rhuMAB-HER-2, possessed antibody-dependent cellular cytotoxicity or ADCC. This underscores that the fact that antibodies capable of binding to the same epitope may not necessarily function in a similar manner. Thus, the synergistic effects may be a function of the particular antibody (i.e. rhuMAB-HER2) in combination with Vinorelbine and not necessarily depend on the epitope to which the antibody is capable of binding.

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Conclusion

Claim 69 is not allowed. Claim 70 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 71 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher Yaen
Art Unit 1643
July 7, 2006


CHRISTOPHER H. YAEN
PRIMARY EXAMINER